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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,195	03/10/2005	Yasufumi Kaneda	GRT/423-69	5170

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EXAMINER	
WILSON, MICHAEL C	
ART UNIT	**PAPER NUMBER**
1632	

MAIL DATE	DELIVERY MODE
08/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,195	KANEDA ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-19-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-7 and 9 are pending.

Election/Restrictions

The restriction requirement has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising a plasmid encoding HGF encapsulated in hemagglutinating virus of Japan envelope protein and treating hearing impairment by administering the composition intrathecally to a patient with hearing impairment, does not reasonably provide enablement for any composition or method as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claim 1 encompasses a composition comprising just the hepatocyte growth factor (HGF) gene for treating hearing impairment. Claims 1 and 2 encompass a composition comprising a plasmid encoding HGF for treating hearing impairment.

The art does not teach how to use the HGF gene alone or a plasmid encoding HGF to treat hearing impairment.

The specification teaches putting plasmid encoding HGF into UV-inactivated hemagglutinating virus of Japan (HVJ) envelope protein (pg 13, 3rd and 4th paragraph). The specification teaches the HGF gene and a plasmid encoding HGF but does not teach provide any guidance regarding how to use them alone for treating hearing impairment. The specification does not teach how to obtain adequate HGF expression using only the HGF gene or plasmid encoding HGF.

Accordingly, it would require those of skill undue experimentation to determine how to treat hearing impairment using only the HGF gene or plasmid encoding HGF gene as encompassed by claims 1 and 2. The product for treating hearing impairment should be limited to a plasmid encoding HGF encapsulated by HVJ envelope protein.

Claim 4 encompasses using envelope protein from Sendai, retrovirus, adenovirus, AAV, herpes virus, vaccinia, pox or influenza virus. The specification does not correlate the results with HVJ envelope protein to any other viral envelope protein. The structure of each viral envelope protein varies significantly. There is no way of predicting whether the results obtained with HVJ envelope protein would be expected in other viral proteins. Therefore, the specification fails to enable envelope protein from any virus in claim 4.

Claim 6 encompasses using the HGF gene to prevent hearing impairment. However, applicants only disclose treating hearing impairment and fail to correlate the method steps with those required to prevent hearing impairment or the temporary expression of HGF to preventing hearing impairment. Without such guidance it would

require those of skill undue experimentation to determine how to use the composition claimed to prevent hearing impairment.

Claim 9 is drawn to treating hearing impairment by administering a HGF gene or plasmid in an amount effective for the treatment. Claim 9 encompasses using just HGF gene or plasmid encoding HGF and is rejected for reasons above. In addition, claim 9 encompasses any route of administration. The teachings in the example are limited to intrathecal administration. The specification does not teach any other way to target the tissue of interest using gene therapy other than intrathecal administration. Accordingly, it would have required those of skill undue experimentation to determine other routes of administration that would target the gene therapy reagent to the tissue of interest and obtain HGF expression in amounts effective to treat hearing impairment. The claims should be limited to intrathecal administration.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite because "a plasmid of a hepatocyte growth factor (HGF) gene" is unclear. HGF genes do not have plasmids.

Claim 3 is indefinite because "a virus envelope vector" does not make sense. While viruses may have or encode envelope proteins, it is unclear how the phrase "virus envelope" further describes a vector.

The phrase "as an active ingredient" in claim 3 is unclear. It is unclear if it is further limiting what is the active ingredient or is referring to the active ingredient in claim 1.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Wu (US Patent Application Publication 2001/0039048 A1, Nov. 8, 2001).

Wu taught a composition comprising a shuttle plasmid encoding HGF (pg 1, paragraph 11) and an adenoviral particle comprising DNA encoding HGF (pg 2, paragraph 28). The adenoviral particle inherently has envelope proteins protecting the DNA encoding HGF, which meets the limitation in claims 3 and 4. The phrases "for hearing impairment" (claim 1), "deafness" (claim 5), "for preventing hearing impairment" (claim 6) and "a therapeutic or ameliorating agent for hearing impairment" (claim 7) are

intended uses and do not bear weight when considering the art because they do not distinguish the structure of the composition claimed over the composition described by Wu. The composition of Wu is a "pharmaceutical composition" as claimed because it is used in vivo.

Claims 1, 2 and 5-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Guo (CN 1358543A, July 17, 2002).

Guo taught a composition comprising a plasmid encoding HGF (see English abstract). The phrases "for hearing impairment" (claim 1), "deafness" (claim 5), "for preventing hearing impairment" (claim 6) and "a therapeutic or ameliorating agent for hearing impairment" (claim 7) are intended uses and do not bear weight when considering the art because they do not distinguish the structure of the composition claimed over the composition described by Wu. The composition of Guo is a "pharmaceutical composition" as claimed because it is used in vivo.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image

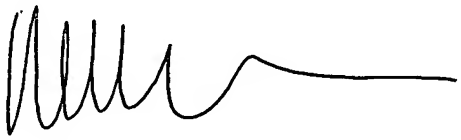
problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER